

From the INTERNATIONAL SEARCHING AUTHORITY

**PCT**

To:

DORSEY & WHITNEY LLP  
Attn: Abelev, Gary ESQ.  
250 Park Avenue  
New York NY 10177  
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY OR THE DECLARATION  
Patent Mail Received

JUL 22 2008

(PCT Rule 44.1)

Date of mailing  
(day/month/year) 18/07/2008

Applicant's or agent's file reference

189148/PCT

**FOR FURTHER ACTION**

See paragraphs 1 and 4 below

International application No.

PCT/US2008/057533

International filing date

(day/month/year) 19/03/2008

Applicant

THE GENERAL HOSPITAL CORPORATION

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

**For more detailed instructions,** see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

**4. Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



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Authorized officer

Josephina Tschu

**DOCKETED**

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 236).

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments?

##### **Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 189148/PCT	<b>FOR FURTHER ACTION</b> see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2008/057533	International filing date (day/month/year) 19/03/2008	(Earliest) Priority Date (day/month/year) 19/03/2007
Applicant  THE GENERAL HOSPITAL CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).  
 c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant  
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1  
☒ as suggested by the applicant  
☐ as selected by this Authority, because the applicant failed to suggest a figure  
☐ as selected by this Authority, because this figure better characterizes the invention  
 b. ☐ none of the figures is to be published with the abstract

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/026 A61B5/00 A61B5/103 G01N21/47 G01P5/00  
G01P3/36

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G01N G01P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 728 440 A (OTT LUTZ [DE]) 28 August 1996 (1996-08-28) the whole document	1,5,6,9
X	US 6 045 511 A (OTT LUTZ [DE] ET AL) 4 April 2000 (2000-04-04) the whole document	1-3
X	AIZU Y ET AL: "BIO-SPECKLE PHENOMENA AND THEIR APPLICATION TO THE EVALUATION OF BLOOD FLOW" OPTICS AND LASER TECHNOLOGY, ELSEVIER SCIENCE PUBLISHERS BV., AMSTERDAM, NL, vol. 23, no. 4, 1 August 1991 (1991-08-01), pages 205-219, XP000262901 ISSN: 0030-3992 the whole document	1,9
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

19 June 2008

Date of mailing of the international search report

18/07/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Anscombe, Marcel

## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/152989 A1 (PUTTAPPA JAYANTH [US] ✓ ET AL PUTTAPPA JAYANTH [US] ET AL) 5 August 2004 (2004-08-05) the whole document	1,9
X	US 5 212 667 A (TOMLINSON JR HAROLD W [US] ✓ ET AL) 18 May 1993 (1993-05-18) the whole document	1,9
X	US 2002/016533 A1 (MARCHITTO KEVIN S [AU] I ET AL) 7 February 2002 (2002-02-07) paragraph [0038]	1,9
X	WO 2005/054780 A (GEN HOSPITAL CORP [US]; YELIN DVIR [US]; BOUMA BRETT E [US]; TEARNEY G) 16 June 2005 (2005-06-16) I the whole document	10,11, 18,19
X	US 2004/126048 A1 (DAVE DIGANT P [US] ET ✓ AL) 1 July 2004 (2004-07-01) paragraph [0052]	10,11,19
X	WO 2007/028531 A (ZEISS CARL MEDITEC AG ✓ [DE]; EVERETT MATTHEW J [US]; ZHOU YAN [US]; MEY) 15 March 2007 (2007-03-15) page 8, line 35 - line 46	10,11,19
Y	WO 98/48846 A (NYCOMED IMAGING AS [NO]; COCKBAIN JULIAN R M [GB]; HOHENSCHUH ERIC ✓ [US] 5 November 1998 (1998-11-05) page 19, paragraph 2	1,7,8, 10-15
Y	WO 03/105678 A (ADVANCED RES & TECH INST ✓ [US]; MILLER DONALD T [US]; JONNAL RAVI ✓ [US] 24 December 2003 (2003-12-24) paragraph [0046]	1,7,8, 10-15
X	RICHARDS G J ET AL: "Laser speckle contrast analysis (LASCA): a technique for measuring capillary blood flow using the ✓ first order statistics of laser speckle patterns" 19970402, 2 April 1997 (1997-04-02), pages 11/1-11/6, XP006510103 the whole document	1-4,10, 14-16
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## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>MARIA M. GONIK, ALEXANDER B. MISHIN,  DMITRY A. ZIMNYAKOV: "Visualization of  Blood Microcirculation Parameters in Human  Tissues by Time-Integrated Dynamic  Speckles Analysis"  ANNALS OF THE NEW YORK ACADEMY OF  SCIENCES,  vol. 972, no. 1, October 2002 (2002-10),  pages 325-330, XP002485050  page 329; figure 1</p> <p>-----</p>	17
A	<p>DAVID A. BOAS, GORO NISHIMURA, ARJUN G.  YODH: "Diffusing temporal light  correlation for burn diagnosis" I  PROC. SPIE,  vol. 2979, 22 March 2005 (2005-03-22),  pages 468-476, XP002485051  the whole document</p> <p>-----</p>	17

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0728440	A	28-08-1996	US 6045511 A	04-04-2000
US 6045511	A	04-04-2000	EP 0728440 A2	28-08-1996
US 2004152989	A1	05-08-2004	NONE	
US 5212667	A	18-05-1993	NONE	
US 2002016533	A1	07-02-2002	US 2005143662 A1	30-06-2005
WO 2005054780	A	16-06-2005	EP 1687587 A1 JP 2007512541 T	09-08-2006 17-05-2007
US 2004126048	A1	01-07-2004	US 2003020920 A1	30-01-2003
WO 2007028531	A	15-03-2007	US 2007103693 A1	10-05-2007
WO 9848846	A	05-11-1998	AU 7221698 A EP 0979107 A1 JP 2001526650 T	24-11-1998 16-02-2000 18-12-2001
WO 03105678	A	24-12-2003	AU 2003245458 A1 US 2006058682 A1	31-12-2003 16-03-2006

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2008/057533

International filing date (day/month/year)  
19.03.2008

Priority date (day/month/year)  
19.03.2007

International Patent Classification (IPC) or both national classification and IPC  
INV. A61B5/026 A61B5/00 A61B5/103 G01N21/47 G01P5/00 G01P3/36

Applicant  
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Date of completion of  
this opinion

see form  
PCT/ISA/210

Authorized Officer

Anscombe, Marcel

Telephone No. +49 89 2399-2490





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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2008/057533

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	<u>2,3,4,6,7,8,12-18</u>
	No: Claims	<u>1,5,9,10,11,19</u>
Inventive step (IS)	Yes: Claims	<u>17</u>
	No: Claims	<u>1-16,18,19</u>
Industrial applicability (IA)	Yes: Claims	<u>1-19</u>
	No: Claims	

2. Citations and explanations

see separate sheet

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

see separate sheet

Reference is made to the following documents:

- D1: EP-A-0 728 440
- D2: US-A-6 045 511
- D3: AIZU Y ET AL: "BIO-SPECKLE PHENOMENA AND THEIR APPLICATION TO THE EVALUATION OF BLOOD FLOW" OPTICS AND LASER TECHNOLOGY, ELSEVIER SCIENCE PUBLISHERS BV., AMSTERDAM, NL, vol. 23, no. 4, 1 August 1991 (1991-08-01), pages 205-219, XP000262901 ISSN: 0030-3992
- D4: US 2004/152989
- D5: US-A-5 212 667
- D6: US 2002/016533
- D7: WO 2005/054780
- D8: US 2004/126048
- D9: WO 2007/028531
- D10: WO 98/48846
- D11: WO 03/105678
- D12: RICHARDS G J ET AL: "Laser speckle contrast analysis (LASCA): a technique for measuring capillary blood flow using the first order statistics of laser speckle patterns" 19970402, 2 April 1997 (1997-04-02), pages 11/1-11/6, XP006510103
- D13: MARIA M. GONIK, ALEXANDER B. MISHIN, DMITRY A. ZIMNYAKOV: "Visualization of Blood Microcirculation Parameters in Human Tissues by Time-Integrated Dynamic Speckles Analysis" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 972, no. 1, October 2002 (2002-10), pages 325-330, XP002485050
- D14: DAVID A. BOAS, GORO NISHIMURA, ARJUN G. YODH: "Diffusing temporal light correlation for burn diagnosis" PROC. SPIE, vol. 2979, 22 March 2005 (2005-03-22), pages 468-476, XP002485051

**Item V**

**1 Art. 6 PCT**

- 1.1 **Claims 1, 9, 12 & 13** do not comply with Art. 6 PCT because the essential features of the device "time intervals" are defined in terms of a result to be achieved "sufficient to measure .... tissue". Such a definition of a device characteristic is unclear because undue experimentation would be required to establish if a device performs in the manner claimed because "tissue" is not a standard item (e.g. compare an elephant

with a mouse). Even in light of the description, which includes the sense "below the skin" the same problem arises: what is a standard skin? The claim should not be so formulated so as to claim the underlying problem but instead comprise technical features which can be comprehended without reference to interactions with non-standard objects, particularly when those are not part of the claimed subject-matter, e.g. "tissue" (Guidelines 4.8a).

- 1.2 **Claims 3 & 15** refer to capillary blood flow, which is not a device feature and therefore unclear.
- 1.3 **Claims 4 & 16** do not refer to any device features in support of "application of pressure to or at the tissue" and are therefore not of a clear category, referring instead to the use to which the device is put.
- 1.4 **Claim 7** does not comply with Art. 6 PCT because "the reference" has no antecedent.
- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **independent claims 1 & 9, 10 & 19** is not new in the sense of Article 33(2) PCT. The reasons are as follows.
  - 2.1 Independent **claims 1 & 9**
    - 2.1.1 Document D1 discloses a system and method for providing information associated with tissue ("Muskelaktivitäten", col. 8, lines 49), comprising: a first arrangement which is configured to illuminate the tissue with at least one electro-magnetic radiation which is at least one of a coherent light or a partially coherent light (partially coherent and coherent, since "kohärenzlänge größer als 10cm" col. 11, lines 7-11); a second arrangement (58) which is configured to receive the at least one electro-magnetic radiation reflected from the tissue and form speckle patterns associated with the at least one electro-magnetic radiation ("Speckle-Muster", col. 4, line 24); and a third arrangement (78) ("Cepstrumanalysefunktion" appears to be a typo meaning "Spektrumanalysefunktion" where in German a "k" would normally be used i.e. "Spektrumanalysefunktion") which is configured to analyze changes in the speckle patterns at time intervals (the effect being measured in D1 is that of frequency changes of intensity fluctuations arising from the Doppler effect which are implicitly associated with a speckle pattern (col. 4, lines 24-26). The frequency changes are evident from an FFT (86),

which is itself performed in the time domain in a non-zero time window (84), having by definition at least two arbitrary time intervals; and in such a way that measurements are taken at time intervals such that "veränderte Frequenzen" and "Spektren mit periodischen Schwankungen einer genauen Analyse unterzogen werden können" can be measured, col. 10, lines 53-57) sufficient to measure motion of ("Bewegungen des Gewebes") or within (implicit) a fascial compartment of the tissue (from "Muskelfasern" and "tieferen Gewebeschichten" and "große Gewebetiefen" col. 5, lines 24-48 it is implicit that device can perform this task, since muscle is analysed at depth such, as located in fascial compartments).

It is additionally indicated, for avoidance of any confusion, that the US family member D2 corresponding to D1 is not a one-to-one translation of D1, for example in D2's omission of references to muscles - as are present in D1 as cited above.

- 2.1.2 The subject-matter of **claims 1 & 9** appears also to be known from the following documents:
  - 2.1.2.1 D3 - which measures the change in speckle pattern of the gastric mucous membrane of a rabbit (fig. 13 and passages related thereto);
  - 2.1.2.2 D4 - "speckle from interior parts of specimen 16" paragraph [0032] & paragraphs [0025-0029];
  - 2.1.2.3 D5 - (4), (10);
  - 2.1.2.4 D6 - paragraph [0038].

**2.2 Independent claims 10 & 19**

The subject-matter of **claim 10 & 19** is not new simply because speckle is present and recorded as a function of depth in standard OCT setups, even though not necessarily a welcome phenomenon - see D7 (page 12, lines 7-18), D8 (paragraph [0052]) and D9 (page 8, lines 29).

**3 Dependent claims**

The dependent claims below listed do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT

in respect of novelty and/or inventive step, the reasons being as follows:

3.1 Novelty

- 3.1.1 The additional subject-matter of **claim 5** is known from document D1 (fig. 1), D13 (fig. 1) and D14 (fig. 3).
- 3.1.2 The subject-matter of **claim 11** is not new in view of the fact that any measurement revealing a speckle pattern, as in D7-D9 cited above, is a measure of the presence of Brownian motion within the sample.

3.2 Inventive step

- 3.2.1 The subject-matter of **claims 2, 3, 14 & 15** is rendered obvious by document D2 ("blood flow", col. 3, line 26) and D12 (abstract and page 11, paragraph 3 referring to fig. 2a and 2b).
- 3.2.2 The additional subject-matter of **claim 6 & 18** is trivial.
- 3.2.3 The additional subject-matter of **claim 4 & 16** is known in the art, for example document D11, page 11, first paragraph.
- 3.2.4 The subject-matter of **claims 7, 8 and 11** appears to be obvious in light of document D10 (page 19, paragraph 2), which anticipates the advantages offered of utilizing speckle pattern data for measurement of motion at various depths, which a skilled person would therefore be motivated to implement according to D11 (paragraph [0046]). For the reasons given concerning Art. 6 PCT, the feature "sufficient to measure .... of the tissue" does not confer any inventive contribution since it is not a clearly defined device feature.

4 **Claim 17**

- 4.1 The subject-matter of **claim 17**, in so far as it can be understood with the help of the description paragraphs [0028-29] & paragraph [0031] appears to meet the requirements of Article 33(1) PCT.
- 4.2 The requirements of Art. 5 PCT are not met by the subject-matter of **claim 17** because of the vagueness of the description concerning how the combined features of "moving the reference" (fig. 7) and "separated from one another by a predetermined distance" (fig. 6) referred to in the invention of **claim 17** are actually carried out and what technical effect the combined features have. The vague references to "utilizing variants ... b) optimizing geometry" (paragraph [0028]) does not clearly disclose any combination of the features of fig. 6 and 7 in a manner sufficiently unambiguous so as to allow a skilled person to carry out methodically the subject-matter of **claim 17** without undue experimentation (Guidelines 5.56, 5.45,

5.47(v) & (vi), 5.53).

**Item VII**

Figure 4 is not clear (Rule 11.13 PCT). This opinion was issued after expiration of the time limit for corrections as issued by the receiving office. At the time of writing, no such corrections were on file.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

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General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
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Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
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Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).
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If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

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Filing informal comments	After receipt of the ISR/ WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
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End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
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Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, QJ 11/2003, QJ 12/2003
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